

K073324

MAR 13 2006

## **510(k) Summary – Medtronic Profile 3D™ Annuloplasty Ring**

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92.

### **I. SUBMITTER INFORMATION**

Company Name: Medtronic Heart Valves (Medtronic)  
Company Address: 8299 Central Avenue N.E.  
Minneapolis, MN 55432  
Company Phone: 763-514-6600  
Company Facsimile: 763-514-6775  
Contact Person: Becky Hannack  
Regulatory Affairs Specialist  
Date Summary Prepared: November 26, 2007

### **II. DEVICE IDENTIFICATION**

Trade/Proprietary Name: Profile 3D™ Annuloplasty Ring, Model 680R  
21 CFR Reference: 870.3800  
21 CFR Common Name: Ring, Annuloplasty  
Classification: Class II  
Panel: CV (74) KRH

### **III. IDENTIFICATION OF PREDICATE DEVICE**

Trade/Proprietary Name: CG Future® Annuloplasty System,  
Model 638R (Ring)  
510(k) Number: K061127  
510(k) Clearance Date: May 23, 2006

### **IV. DEVICE DESCRIPTION**

The Profile 3D™ Annuloplasty Ring, Model 680R, consists of a titanium core overmolded with silicone and covered with polyester fabric. The ring must be implanted in the mitral position. The ring is marked at three points by colored

sutures; two markers correspond to the trigones of the mitral valve and one identifies the midpoint of the device. The device size is identified by the inside diameter of the ring at its widest point. The titanium core enables radiographic visualization of the device.

## **V. DESCRIPTION OF INTENDED USE**

The Profile 3D™ Annuloplasty Ring is indicated for the reconstruction and/or remodeling of pathological mitral valves. Valvular insufficiency and/or stenosis may be corrected by appropriate repair and annular remodeling.

## **VI. SUBSTANTIAL EQUIVALENCE**

The Profile 3D™ Annuloplasty Ring is substantially equivalent to the predicate device, the CG Future® Annuloplasty Ring. They have the same fundamental scientific technology and intended use.

## **VII. PERFORMANCE DATA**

The Profile 3D™ Annuloplasty Ring was subjected to verification and validation studies. These verification/validation studies demonstrate the modifications to the predicate device are appropriate and do not affect the intended use or performance of the device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 13 2008

Medtronic Heart Valves  
c/o Ms. Becky Hannack  
Regulatory Affairs Specialisty  
8299 Central Avenue NE  
Minneapolis, MN 55432

Re: K073324  
Medtronic Profile 3D™ Annuloplasty Ring, Model 680R  
Regulation Number: 870.3800  
Regulation Name: Ring, Annuloplasty  
Regulatory Class: Class II (two)  
Product Code: KRH  
Dated: January 10, 2008  
Received: January 11, 2008

Dear Ms. Hannack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

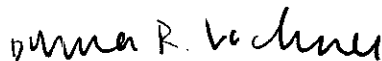
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K073324

Device Name: Medtronic PROFILE 3D Annuloplasty Ring, Model 680R

### Indications For Use:

The PROFILE 3D Ring is indicated for the reconstruction and/or remodeling of pathological mitral valves. Valvular insufficiency and/or stenosis may be corrected by appropriate repair and annular remodeling.

Prescription Use   x    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Donna R. Lechner*  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K073324

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